

Remarks

Claims 1-54 and 56-78 are pending for the Examiner's consideration, including amended claim 41 and new claims 56-78. No new matter is believed to have been added.

Presentation of New Claims 56-78

Upon review, Applicants believe that pending claims in the present application, e.g. independent claims 1, 40 and 41, are directed to subject matter that is similar to subject matter that concurrently was covered by the claims in co-pending application no. 09/814,224 ("the '224 application").¹ Applicants recently canceled the pending claims in the '224 application² and are now presenting similar claims herein as new claims 56-78.

Applicants note that the '114 application is being examined by a different examiner from the present application. Should the Examiner of the present application require any further information concerning this matter, a personal or telephonic interview is respectfully requested to discuss any remaining issues and accelerate the prosecution of the present application.

Claim to Priority

The Office Action states that "[t]he Examiner has acknowledged the claim to priority under provisional application no. 60/191,099 filed on March 22, 2000." (Office Action, April 22, 2003, page 3). Applicants respectfully request that the Examiner further indicate such acknowledgment on an Office Action Summary under the heading "Priority under 35 U.S.C. §§ 119 and 120."

Information Disclosure Statements

A Second Information Disclosure Statement was filed by Applicants on October 22, 2002, and a Third Information Disclosure Statement was filed by Applicants on April 15, 2003. Applicants respectfully request that the disclosed references be made of

¹ A copy of U.S. Patent Application Publication No. US 2001/0041941 A1, corresponding to the '224 application, was filed in a Third Information Disclosure Statement dated April 15, 2003.

² Applicants note that the '224 application was subject to an election/restriction requirement, however no further Office Action issued on the merits of the claims. According to the Examiner, the claims did not read on the elected species. In a Supplemental Response to Restriction Requirement filed September 17, 2003, Applicants recently presented new claims in the '224 application and provisionally elected to prosecute the species of Fig. 16 with respect to the new claims.

record in this application, and that the Examiner complete and return initialed Forms PTO-1449.

Claim Rejections

1. The Term "Sheath"

Claims 1-2, 5-15, 17-22, 25-39, 41-43, and 48-54 were rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,899,939 to Boyce *et al.* ("Boyce"). In addition, claims 3-4, 16, 23-24, 40, and 44-47 were rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over Boyce in view of U.S. Patent No. 4,950,296 to McIntyre ("McIntyre"). The rejections respectfully are traversed.

In the Office Action, the Examiner stated:

The Applicant has argued that Boyce does not disclose inner and outer sheaths, layers in fig. 2 forming a sheath with an opening defining an interior surface, or at least two layers of bone components coupled together. In response, *Webster's II New Riverside University Dictionary* defines a sheath as "a covering". Boyce discloses layers forming what the Examiner is interpreting as "sheaths" in that they provide a covering for layers in between (fig. 2). Boyce further discloses a sheath having an opening defining an interior surface (fig. 1 and col. 6, lines 14-18) and at least two layers of bone components coupled together (col. 4, lines 1-33).

(Office Action, April 22, 2003, page 3).

Applicants respectfully disagree.

As used by Applicants, and as defined in THE AMERICAN HERITAGE COLLEGE DICTIONARY, THIRD EDITION, p. 1254 (1997), the term "sheath" refers to "an enveloping tubular structure." Moreover, claims must be read in light of the disclosure of the specification on which they are based, not in a vacuum. *In re Dean*, 291 F.2d 947 (C.C.P.A. 1961). Applicants specification, for example, states at page 12, lines 35-36 that "FIG. 1G shows a first embodiment of implant 16 having an outer sheath 17, an intermediary sheath 18, and a core 19." The specification also states at page 15, lines 6-7 that "[b]one stock 25' is preferably solid, and formed by fitting a smaller diameter bone core *within* at least one larger diameter sheath." (Emphasis added). Clearly, as used in the specification and shown in the figures, the term sheath is to be construed as an enveloping tubular structure.

The Office Action states that "Boyce discloses layers forming what the Examiner is interpreting as 'sheaths' in that they provide a covering for layers in between (fig. 2)." (Office Action, April 22, 2003, page 3). But Boyce discloses an implant construction in which "multi-sectional layers [are] built up from two or more subsections, e.g., joined to each other in edge-to-edge fashion in a manner which is analogous to

planking." (Boyce., Col. 2, lines 58-62) (emphasis added). Clearly, the planking of Boyce does not involve sheaths, e.g., enveloping tubular structures, as recited by Applicants in independent claims 1, 21, and 40.

2. Fig. 1 of Boyce

The Office Action states:

The Applicant has argued that Boyce does not disclose an implant. In response, Boyce clearly discloses that the device is directed to bone-derived implants (col. 1, line 65 to col. 2, line 40).

(Office Action, April 22, 2003, page 3).

Applicants have made no such argument. In point of fact, Applicants refer the Examiner to the specification of the Boyce patent which clearly states that Fig. 1 of Boyce shows *the diaphyseal region (i.e., the shaft region) of a bone 10*. Furthermore, as described in Boyce, the cortical portion of bone 10 taken from the diaphyseal region is cut into cortical bone layers 11 of varying width by slicing the bone longitudinally. (Boyce, Col. 5, lines 62-65). Thus, *Fig. 1* of Boyce does not disclose an implant -- it simply discloses the shaft region of a bone.

The Office Action states that with respect to claim 40, "Boyce further discloses a core fit in an innermost of sheaths (*fig. 1*)."

 (Office Action, April 22, 2003, page 3) (emphasis added). Again, as discussed above, *Fig. 1* of Boyce does not disclose an implant. Thus, as understood, Boyce fails to disclose, much less suggest, the implant recited by Applicants in claim 40.

3. Independent Claim 41

Claim 41 has been amended to recite, *inter alia*, that the implant is formed from at least two different bones selected from a femur, tibia, humerus, fibula, ulna, and radius. With respect to claim 41, the Office Action states that "Boyce further discloses . . . the implant being formed of at least two different bones (col. 4, lines 20-33)." (Office Action, April 22, 2003, page 2). Applicants respectfully disagree. The portion of Boyce cited in the Office Action states:

In addition to its compression strength-imparting fully mineralized or partially mineralized cortical bone layers, the bone-derived implant of this invention can optionally possess one or more layers formed from one or more other materials. For example, these optional layers can be based on or include highly or fully demineralized bone . . .

It is Applicants' position that this section of Boyce fails to provides any suggestion to form an implant from at least two different bones selected from a femur, tibia, humerus, fibula,

ulna, and radius. In contrast, the cited section of Boyce discusses layers of different degrees of mineralization.

Conclusion

In view of the foregoing, it is believed that all the pending claims are in condition for allowance, which is respectfully requested. If the Examiner does not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues so as to expedite the eventual allowance of the claims.

A fee is believed to be due for the presentation of new claims and a Fee Transmittal Sheet is submitted concurrently herewith. A fee for an extension of time also is believed to be due for this submission and a petition for extension of time is submitted concurrently herewith. Should any additional fees be required, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

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Respectfully Submitted,

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Enclosures